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SEC Filings

10-K

BAXTER INTERNATIONAL INC filed this Form 10-K on 02/23/12

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2011

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____
 Commission file number 1-4448

Baxter
Baxter International Inc.

*(Exact Name of Registrant as Specified in its Charter)***Delaware***(State or Other Jurisdiction of
Incorporation or Organization)*

One Baxter Parkway, Deerfield, Illinois
(Address of Principal Executive Offices)

36-0781620*(I.R.S. Employer Identification No.)***60015***(Zip Code)***Registrant's telephone number, including area code 847.948.2000****Securities registered pursuant to Section 12(b) of the Act:**Title of Each ClassName of Each Exchange on Which Registered

Common stock, \$1.00 par value

New York Stock Exchange
 Chicago Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
 Indicate by check mark whether registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) Yes ☒ No ☐
 Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒Accelerated filer ☐Non-accelerated filer ☐Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of June 30, 2011 (the last business day of the registrant's most recently completed second fiscal quarter), based on the per share closing sale price of \$59.69 on that date and the assumption for the purpose of this computation only that all of the registrant's directors and executive officers are affiliates, was approximately \$34 billion. There is no non-voting common equity held by non-affiliates of the registrant.

The number of shares of the registrant's common stock, \$1.00 par value, outstanding as of January 31, 2012 was 560,346,203.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive 2012 proxy statement for use in connection with its Annual Meeting of Shareholders to be held on May 8, 2012 are incorporated by reference into Part III of this report.

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PART I**Item 1. Business.****Company Overview**

Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide. These products are used by hospitals, kidney dialysis centers, nursing homes, rehabilitation centers, doctors' offices, clinical and medical research laboratories, and by patients at home under physician supervision. Baxter manufactures products in 27 countries and sells them in more than 100 countries.

Baxter International Inc. was incorporated under Delaware law in 1931. As used in this report, except as otherwise indicated in information incorporated by reference, "Baxter International" means Baxter International Inc. and "Baxter," the "company" or the "Company" means Baxter International and its consolidated subsidiaries.

Business Segments and Products

Prior to 2011, the company operated in three segments: BioScience, Medication Delivery and Renal. The company has combined its former Medication Delivery and Renal businesses into a single global business unit to form the Medical Products business. Effective January 1, 2011, the company changed its segment presentation to reflect this new structure, and recast all prior periods presented to conform to the new presentation. The company's continuing operations are comprised of the BioScience and Medical Products segments.

BioScience. The BioScience business processes recombinant and plasma-based proteins to treat hemophilia and other bleeding disorders; plasma-based therapies to treat immune deficiencies, alpha-1 antitrypsin deficiency, burns and shock, and other chronic and acute blood-related conditions; products for regenerative medicine, such as biosurgery products; and select vaccines.

Medical Products. The Medical Products business manufactures intravenous (IV) solutions and administration sets, premixed drugs and drug-reconstitution systems, pre-filled vials and syringes for injectable drugs, IV nutrition products, infusion pumps, and inhalation anesthetics. The business also provides products and services related to pharmacy compounding, drug formulation and packaging technologies. In addition, the Medical Products business provides products and services to treat end-stage renal disease, or irreversible kidney failure. The business manufactures solutions and other products for peritoneal dialysis (PD), a home-based therapy, and also distributes products for hemodialysis, which is generally conducted in a hospital or clinic.

For financial information about Baxter's segments and principal product categories, see Note 12 in Item 8 of this Annual Report on Form 10-K.

Sales and Distribution

The company has its own direct sales force and also makes sales to and through independent distributors, drug wholesalers acting as sales agents and specialty pharmacy or homecare companies. In the United States, Cardinal Health, Inc. warehouses and ships a significant portion of the company's products through its distribution centers. These centers are generally stocked with adequate inventories to facilitate prompt customer service. Sales and distribution methods include frequent contact by sales representatives, automated communications via various electronic purchasing systems, circulation of catalogs and merchandising bulletins, direct-mail campaigns, trade publication presence and advertising.

International sales are made and products are distributed on a direct basis or through independent local distributors or sales agents in more than 100 countries.

International Operations

Baxter products are manufactured and sold worldwide. Approximately 60% of the company's revenues are generated outside of the United States and geographic expansion remains a core component of the company's strategy. Baxter's international presence includes operations in Europe, Asia-Pacific, Latin America and Canada. The company is subject to certain risks inherent in conducting business outside the United States. For more information on these risks, see the information under the captions "We are subject to risks associated with doing business globally" and "We are subject to foreign currency exchange risk" in Item 1A of this Annual Report on Form 10-K, all of which information is incorporated herein by reference.

For financial information about foreign and domestic operations and geographic information, see Note 12 in Item 8 of this Annual Report on Form 10-K. For more information regarding foreign currency exchange risk, refer to the discussion under the caption entitled "Financial Instrument Market Risk" in Item 7 of this Annual Report on Form 10-K.

Contractual Arrangements

Substantial portions of the company's products are sold through contracts with customers, both within and outside the United States. Some of these contracts have terms of more than one year and place limits on the company's ability to increase prices. In the case of hospitals, governments and other facilities, these contracts may specify minimum quantities of a particular product or categories of products to be purchased by the customer.

In keeping with the increased emphasis on cost-effectiveness in healthcare delivery, many hospitals and other customers of medical products in the United States and in other countries have joined group purchasing organizations (GPOs), or formed integrated delivery networks (IDNs), to enhance purchasing power. GPOs and IDNs negotiate pricing arrangements with manufacturers and distributors, and the negotiated prices are made available to members. Baxter has purchasing agreements with several of the major GPOs in the United States. GPOs may have agreements with more than one supplier for certain products. Accordingly, in these cases, Baxter faces competition from other suppliers even where a customer is a member of a GPO under contract with Baxter.

Raw Materials

Raw materials essential to Baxter's business are purchased from numerous suppliers worldwide in the ordinary course of business. Although most of these materials are generally available, certain raw materials used in producing some of the company's products are available only from one or a limited number of suppliers, and Baxter at times may experience shortages of supply. In an effort to manage risk associated with raw materials supply, Baxter works closely with its suppliers to help ensure availability and continuity of supply while maintaining high quality and reliability. The company also seeks to develop new and alternative sources of supply where beneficial to its overall raw materials procurement strategy. In order to produce plasma-based therapies, the company also collects plasma at numerous collection facilities in the United States. For more information on plasma collection, refer to the discussion under the caption "The nature of producing plasma-based therapies may prevent us from timely responding to market forces and effectively managing our production capacity" in Item 1A of this Annual Report on Form 10-K.

The company also utilizes long-term supply contracts with some suppliers to help maintain continuity of supply and manage the risk of price increases. Baxter is not always able to recover cost increases for raw materials through customer pricing due to contractual limits and market forces.

Competition and Healthcare Cost Containment

Baxter's BioScience and Medical Products businesses enjoy leading positions based on a number of competitive advantages. The BioScience business benefits from continued innovation in its products and therapies, consistency of its supply of products, and strong customer relationships. The Medical Products business benefits from the breadth and depth of its product offering, as well as strong relationships with customers, including hospitals, customer purchasing groups and pharmaceutical and biotechnology companies. The Medical Products business also benefits from its position as one of the world's leading manufacturers of PD products, as well as its strong relationships with customers and patients, including the many patients who self-administer the home-based therapy supplied by Baxter. Baxter as a whole benefits from efficiencies and cost advantages resulting from shared manufacturing facilities and the technological advantages of its products.

Although no single company competes with Baxter in all of its businesses, Baxter faces substantial competition in each of its segments from international and domestic healthcare and pharmaceutical companies of all sizes. BioScience continues to face competitors from pharmaceutical, biotechnology and other companies. Medical Products faces competition from medical device manufacturers and pharmaceutical companies. In addition, global and regional competitors continue to expand their manufacturing capacity for PD products and their PD sales and marketing channels. Competition is primarily focused on cost-effectiveness, price, service, product performance, and technological innovation. There has been increasing consolidation in the company's customer base and by its competitors, which continues to result in pricing and market share pressures.

Global efforts toward healthcare cost containment continue to exert pressure on product pricing. Governments around the world use various mechanisms to control healthcare expenditures, such as price controls, product formularies (lists of recommended or approved products), and competitive tenders which require the submission of a bid to sell products. Sales of Baxter's products are dependent, in part, on the availability of reimbursement by government agencies and healthcare programs, as well as insurance companies and other private payers. In the United States, the federal and many state governments have adopted or proposed initiatives relating to Medicaid and other health programs that may limit reimbursement or increase rebates that Baxter and other providers are required to pay to the state. In addition to government regulation, managed care organizations in the United States, which include medical insurance companies, medical plan administrators, health-maintenance organizations, hospital and physician alliances and pharmacy benefit managers, continue to put pressure on the price and usage of healthcare products. Managed care organizations seek to contain healthcare expenditures, and their purchasing strength has been increasing due to their consolidation into fewer, larger organizations and a growing number of enrolled patients. Baxter faces similar issues outside of the United States. In Europe and Latin America, for example, the government provides healthcare at low cost to patients, and controls its expenditures by purchasing products through public tenders, regulating prices, setting reference prices in public tenders or limiting reimbursement or patient access to certain products.

Intellectual Property

Patents and other proprietary rights are essential to Baxter's business. Baxter relies on patents, trademarks, copyrights, trade secrets, know-how and confidentiality agreements to develop, maintain and strengthen its competitive position. Baxter owns a number of patents and trademarks throughout the world and has entered into license arrangements relating to various third-party patents and technologies. Products manufactured by Baxter are sold primarily under its own trademarks and trade names. Some products distributed by the company are sold under the company's trade names, while others are sold under trade names owned by its suppliers. Trade secret protection of unpatented confidential and proprietary information is also important to Baxter. The company maintains certain details about its processes, products and technology as trade secrets and generally requires employees, consultants, parties to collaboration agreements and other business partners to enter into confidentiality agreements.

Baxter's policy is to protect its products and technology through patents and trademarks on a worldwide basis. This protection is sought in a manner that balances the cost of such protection against obtaining the greatest value

for the company. Baxter also recognizes the need to promote the enforcement of its patents and trademarks and takes commercially reasonable steps to enforce its patents and trademarks around the world against potential infringers, including judicial or administrative action where appropriate.

Baxter operates in an industry susceptible to significant patent litigation. At any given time, the company is involved as either a plaintiff or defendant in a number of patent infringement and other intellectual property-related actions. Such litigation can result in significant royalty or other payments or result in injunctions that can prevent the sale of products. For more information on patent and other litigation, see Note 11 in Item 8 of this Annual Report on Form 10-K.

Research and Development

Baxter's investment in research and development (R&D) is essential to its future growth and its ability to remain competitive in each of its business segments. Accordingly, Baxter continues to focus its investment in R&D programs to enhance future growth through clinical differentiation. Expenditures for Baxter's R&D activities were \$946 million in 2011, \$915 million in 2010 and \$917 million in 2009. These expenditures include costs associated with R&D activities performed at the company's R&D centers located around the world, which include facilities in Austria, Belgium, Japan and the United States, as well as in-licensing, milestone and reimbursement payments made to partners for R&D work performed at non-Baxter locations.

The company's research efforts emphasize self-manufactured product development, and portions of that research relate to multiple product categories. Baxter supplements its own R&D efforts by acquiring various technologies and entering into development and other collaboration agreements with third parties. In July 2011, Baxter established Baxter Ventures, a strategic initiative to invest up to \$200 million in early-stage companies developing products and therapies to accelerate innovation and growth for the company. For more information on the company's R&D activities, refer to the discussion under the caption entitled "Strategic Objectives" contained in Item 7 of this Annual Report on Form 10-K.

Quality Management

Baxter's success depends upon the quality of its products. Quality management plays an essential role in determining and meeting customer requirements, preventing defects, improving the company's products and services and maintaining the integrity of the data that supports the safety and efficacy of the company's products. Baxter has one quality system deployed globally that enables the design, development, manufacturing, packaging, sterilization, handling, distribution and labeling of the company's products to ensure they conform to customer requirements. In order to continually improve the effectiveness and efficiency of the quality system, various measurements, monitoring and analysis methods such as management reviews, internal, external and vendor audits are employed at local and central levels.

Each product that Baxter markets is required to meet specific quality standards, both in packaging and in product integrity and quality. If either of those is determined to be compromised at any time, Baxter takes necessary corrective and preventative actions, such as notification of the customer of revised labeling, correction of the product at the customer location, withdrawal of the product from the market and other actions. For more information on corrective actions taken by Baxter, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K.

Government Regulation

The operations of Baxter and many of the products manufactured or sold by the company are subject to extensive regulation by numerous government agencies, both within and outside the United States. In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States. While this legislation provides for a number of changes in how companies are compensated for providing healthcare products and services, many of

these changes will be implemented by regulations which have yet to be established. For more information on the expected impact of healthcare reform on the company, refer to the information under the caption "The implementation of healthcare reform in the United States may adversely affect our business" in Item 1A of this Annual Report on Form 10-K.

In the United States, the federal agencies that regulate the company's facilities, operations, employees, products (their manufacture, sale, import and export) and services include: the U.S. Food and Drug Administration (FDA), the Drug Enforcement Agency, the Environmental Protection Agency, the Occupational Health & Safety Administration, the Department of Agriculture, the U.S. Department of Justice (DOJ), the Department of Labor, the Department of Defense, Customs and Border Protection, the Department of Commerce, the Department of Treasury and others. Because Baxter supplies products and services to healthcare providers that are reimbursed by federally funded programs such as Medicare, its activities are also subject to regulation by the Center for Medicare/Medicaid Services and enforcement by the Office of the Inspector General within the Department of Health and Human Services (OIG). State agencies in the United States also regulate the facilities, operations, employees, products and services of the company within their respective states. Outside the United States, the company's products and operations are subject to extensive regulation by government agencies, including the European Medicines Agency (EMA) in the European Union. International government agencies also regulate public health, product registration, pricing, manufacturing, environmental conditions, labor, exports, imports and other aspects of the company's global operations.

The FDA in the United States, the EMA in Europe, and other government agencies inside and outside of the United States, administer requirements covering the testing, safety, effectiveness, manufacturing, labeling, promotion and advertising, distribution and post-market surveillance of Baxter's products. The company must obtain specific approval from the FDA and non-U.S. regulatory authorities before it can market and sell most of its products in a particular country. Even after the company obtains regulatory approval to market a product, the product and the company's manufacturing processes are subject to continued review by the FDA and other regulatory authorities worldwide.

The company is subject to possible administrative and legal actions by the FDA and other regulatory agencies inside and outside the United States. Such actions may include warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. From time to time, the company takes steps to ensure safety and efficacy of its products, such as removing products from the market found not to meet applicable requirements and improving the effectiveness of quality systems. For more information on compliance actions taken by the company, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K.

Environmental policies of the company require compliance with all applicable environmental regulations and contemplate, among other things, appropriate capital expenditures for environmental protection.

Employees

As of December 31, 2011, Baxter employed approximately 48,500 people.

Available Information

Baxter makes available free of charge on its website at www.baxter.com its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), as soon as reasonably practicable after electronically filing or furnishing such material to the Securities and Exchange Commission.

In addition, Baxter's Corporate Governance Guidelines, Code of Conduct, and the charters for the required committees of Baxter's board of directors are available on Baxter's website at www.baxter.com under "Corporate Governance" and in print upon request by writing to: Corporate Secretary, Baxter International Inc., One Baxter Parkway, Deerfield, Illinois 60015. Information contained on Baxter's website shall not be deemed incorporated into, or to be a part of, this Annual Report on Form 10-K.

Item 1A. Risk Factors.

In addition to the other information in this Annual Report on Form 10-K, shareholders or prospective investors should carefully consider the following risk factors. If any of the events described below occurs, our business, financial condition and results of operations and future growth prospects could suffer.

If we are unable to successfully introduce new products or fail to keep pace with advances in technology, our business, financial condition and results of operations could be adversely affected.

We operate in highly competitive and innovative businesses. We need to successfully introduce new products to achieve our strategic business objectives. The development and acquisition of innovative products and technologies that improve efficacy, safety, patients' and clinicians' ease of use and cost-effectiveness involve significant technical and business risks. The success of new product offerings will depend on many factors, including our ability to properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory approvals on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economic and timely manner, and differentiate our products from those of our competitors. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers' requirements, our products may become obsolete and our business could suffer.

We are subject to a number of existing laws and regulations, non-compliance with which could adversely affect our business, financial condition and results of operations, and we are susceptible to a changing regulatory environment.

As a participant in the healthcare industry, our operations and products, and those of our customers, are regulated by numerous government agencies, both inside and outside the United States. The impact of this on us is direct, to the extent we are subject to these laws and regulations, and indirect in that in a number of situations, even though we may not be directly regulated by specific healthcare laws and regulations, our products must be capable of being used by our customers in a manner that complies with those laws and regulations.

Any new product must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. Our facilities must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of the FDA or other regulatory authorities, including a failed inspection or a failure in our adverse event reporting system, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could cause a loss of customer confidence in us and our products, which could adversely affect our sales. In addition, requirements of the FDA and other regulatory authorities are subject to change and compliance with additional requirements may result in product launch delays and otherwise increase our costs.

We continue to address a number of regulatory issues as discussed further under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K. In connection with these issues, there can be no assurance that additional costs or civil and criminal penalties will not be incurred, that additional regulatory actions with respect to the company will not occur, that the company will not face civil claims for damages from purchasers or users, that substantial additional charges or significant asset impairments may not be required, that sales of other products may not be adversely affected, or that additional regulation will not be introduced that may adversely affect the company's operations and consolidated financial statements.

The sales and marketing of products and relationships that pharmaceutical and medical device companies have with healthcare providers are under increasing scrutiny by federal, state and foreign government agencies. The FDA, OIG, DOJ and the Federal Trade Commission have each increased their enforcement efforts (including joint efforts) with respect to the Anti-Kickback Statute, False Claims Act, off-label promotion of products, other healthcare related laws, antitrust and other competition laws. The DOJ also has increased its focus on the enforcement of the U.S. Foreign Corrupt Practices Act (FCPA), particularly as it relates to the conduct of pharmaceutical companies. Foreign governments have also increased their scrutiny of pharmaceutical companies' sales and marketing activities and relationships with healthcare providers. The laws and standards governing the promotion, sale and reimbursement of our products and those governing our relationships with healthcare providers and governments can be complicated, are subject to frequent change and may be violated unknowingly. We have compliance programs in place, including policies, training and various forms of monitoring, designed to address these risks. Nonetheless, these programs and policies may not always protect us from conduct by individual employees that violate these laws. Violations, or allegations of violations, of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have an adverse effect on our business, financial condition and results of operations. For more information related to the Company's ongoing government investigations, please refer to Note 11 in Item 8 of this Annual Report on Form 10-K.

Issues with product quality could have an adverse effect upon our business, subject us to regulatory actions and costly litigation and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality management plays an essential role in determining and meeting customer requirements, preventing defects, improving the company's products and services and maintaining the integrity of the data that supports the safety and efficacy of our products. Our future operating results will depend on our ability to maintain and continuously improve our quality management program, that includes an objective and systematic process for monitoring and the evaluation of key effectiveness indicators. While we have one quality system deployed globally that covers the lifecycle of our products, quality and safety issues may occur with respect to any of our products. Unaffiliated third party suppliers provide a number of goods and services to our R&D, clinical and manufacturing organizations. Third party suppliers are required to comply with our quality standards. Failure of a third party supplier to provide compliant raw materials or supplies could result in delays, service interruptions or other quality related issues that may negatively impact our business results. In addition, some of the raw materials employed in our production processes are derived from human and animal origins, requiring robust controls to eliminate the potential for introduction of pathogenic agents or other contaminants.

A quality or safety issue could have an adverse effect on our business, financial condition and results of operations and may result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products.

For more information on regulatory matters currently being addressed by the company, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K.

Implementation of the FDA order to recall our COLLEAGUE infusion pumps in the United States may adversely affect our business.

Pursuant to the Consent Decree entered into by the company in June 2006, the FDA issued a final order in July 2010 regarding the recall of the company's COLLEAGUE infusion pumps currently in use in the United States. The company is executing the recall by offering its customers an option to replace their COLLEAGUE infusion

pumps or receive monetary consideration. Under the replacement option, the company's customers may receive the Sigma International General Medical Apparatus, LLC (SIGMA) Spectrum infusion pumps in exchange for their COLLEAGUE infusion pumps. For more information on the COLLEAGUE recall, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K. The company cannot be certain that SIGMA will have sufficient production capacity to meet the demand for SIGMA Spectrum infusion pumps. Customers choosing a refund or for whom sufficient replacement pumps are unavailable are likely to move to a competitive infusion pump platform. Many of the company's COLLEAGUE customers also purchase a variety of products from the company's Medical Products business. If a significant number of COLLEAGUE customers move to a competitive pump platform, our business may suffer and sales of other products in the company's Medical Products portfolio may be adversely affected. In addition, it is possible that substantial additional cash and non-cash charges, including significant asset impairments related to the COLLEAGUE infusion pumps and related businesses, may be required in future periods based on new information, changes in estimates, the implementation of the recall in the United States, and other actions the company may be required to undertake in markets outside the United States.

The implementation of healthcare reform in the United States may adversely affect our business.

The Patient Protection and Affordable Care Act (Act), which was signed into law in March 2010, includes several provisions which impact the company's businesses in the United States, including increased Medicaid rebates and an expansion of the 340B Drug Pricing Program which provides certain qualified entities, such as hospitals serving disadvantaged populations, with discounts on the purchase of drugs for outpatient use and an excise tax on the sale of certain drugs and medical devices. In 2011, the company became subject to a tax on the sales of its pharmaceutical products to the government. In 2013, the company will be required to pay a 2.3% tax on sales of certain of its medical devices. The impact of the increased Medicaid rebates and the expanded 340B Drug Pricing Program is largely expected to impact the company's BioScience business, while the additional taxes are expected to impact both of the company's business segments. We may also experience downward pricing pressure as the Act reduces Medicare and Medicaid payments to hospitals. While it is intended to expand health insurance coverage and increase access to medical care generally, the long-term impact of the Act on our business and the demand of our products is uncertain. Similarly, we cannot predict the impact of the additional regulations that need to be established to implement many of the Act's provisions.

If reimbursement for our current or future products is reduced or modified in the United States or abroad, our business could suffer.

Sales of our products depend, in part, on the extent to which the costs of our products are paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, private health coverage insurers and other third-party payors. These healthcare management organizations and third-party payors are increasingly challenging the prices charged for medical products and services. We may continue to experience continued downward pricing pressures from third-party payors which could result in an adverse effect on our business, financial condition and operational results.

The imposition of austerity measures or other reforms by foreign governments may limit, reduce or eliminate payments for our products and adversely affect both our pricing flexibility and demand for our products. Accordingly, our current and future products may not be considered cost effective, and reimbursement to the consumer may not be available or sufficient to allow us to sell our products on a competitive basis. Legislation and regulations affecting reimbursement for our products may change at any time and in ways that are difficult to predict and these changes may be adverse to us.

We face substantial competition across each of our product categories.

Although no single company competes with us in all of our businesses, we face substantial competition in both of our segments from international and domestic healthcare and pharmaceutical companies of all sizes. Competition

is primarily focused on cost-effectiveness, price, service, product performance, and technological innovation. Competition may increase further as additional companies begin to enter our markets or modify their existing products to compete directly with ours. If our competitors respond more quickly to new or emerging technologies and changes in customer requirements, our products may be rendered obsolete or non-competitive. If our competitors develop more effective or affordable products, or achieve earlier patent protection or product commercialization than we do, our operations will likely be negatively affected. If we are forced to reduce our prices due to increased competition, our business will become less profitable. The company's sales could be adversely affected if any of its contracts with group purchasing organizations, integrated delivery networks or other customers are terminated due to increased competition or otherwise.

We also face competition for marketing, distribution and collaborative development agreements, for establishing relationships with academic and research institutions, and for licenses to intellectual property. In addition, academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for discovery, research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs. If we are unable to successfully compete with these companies and institutions, our business may suffer.

The nature of producing plasma-based therapies may prevent us from timely responding to market forces and effectively managing our production capacity.

The production of plasma-based therapies is a lengthy and complex process. Efforts to increase the collection of plasma or the production of plasma-based therapies may include the construction and regulatory approval of additional plasma collection facilities and/or plasma fractionation facilities, which can be a lengthy regulatory and capital intensive process. As a result, our ability to match our collection and production of plasma-based therapies to market demand is imprecise and may result in a failure to meet the market demand for our plasma-based therapies or potentially an oversupply of inventory. Failure to meet market demand for our plasma-based therapies may result in customers transitioning to available competitive products resulting in a loss of segment share or customer confidence. In the event of an oversupply we may be forced to lower the prices we charge for some of our plasma-based therapies, close collection and processing facilities, record asset impairment charges or take other action which may adversely affect our business, financial condition and results of operations.

If we are unable to obtain sufficient components or raw materials on a timely basis or if we experience other manufacturing difficulties, our business may be adversely affected.

The manufacture of our products requires the timely delivery of sufficient amounts of quality components and materials. We manufacture our products in more than 50 manufacturing facilities around the world. We acquire our components and materials from many suppliers in various countries. While efforts are made to diversify our sources of components and materials, in certain instances we acquire components and materials from a sole supplier. We work closely with our suppliers to ensure the continuity of supply but we cannot guarantee these efforts will always be successful. In addition, due to the regulatory environment in which we operate, we may be unable to quickly establish additional or replacement sources for some components or materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our products in a timely or cost-effective manner, and our ability to make product sales.

Many of our products are difficult to manufacture. This is due to the complex nature of manufacturing pharmaceuticals, including biologics, and devices, as well as the strict regulatory regime governing our manufacturing operations. Variations in the manufacturing process may result in production failures which could lead to launch delays, product shortage, unanticipated costs, lost revenues and damage to our reputation.

A failure to identify and address manufacturing problems prior to the release of products to our customers may also result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals or licenses.

Several of our products are manufactured at a single manufacturing facility. Loss or damage to a manufacturing facility due to a natural disaster or otherwise could adversely affect our ability to manufacture sufficient quantities of key products to meet customer demand or contractual requirements which may result in a loss of revenue and other adverse business consequences. Because of the time required to approve and license a manufacturing facility a third party manufacturer may not be available on a timely basis to replace production capacity in the event we lose manufacturing capacity due to natural disaster, regulatory action or otherwise.

If we are unable to protect our patents or other proprietary rights, or if we infringe the patents or other proprietary rights of others, our competitiveness and business prospects may be materially damaged.

Patent and other proprietary rights are essential to our business. Our success depends to a significant degree on our ability to obtain and enforce patents and licenses to patent rights, both in the United States and in other countries. We cannot guarantee that pending patent applications will result in issued patents, that patents issued or licensed will not be challenged or circumvented by competitors, that our patents will not be found to be invalid or that the intellectual property rights of others will not prevent the company from selling certain products or including key features in the company's products.

The patent position of a healthcare company is often uncertain and involves complex legal and factual questions. Significant litigation concerning patents and products is pervasive in our industry. Patent claims include challenges to the coverage and validity of our patents on products or processes as well as allegations that our products infringe patents held by competitors or other third parties. A loss in any of these types of cases could result in a loss of patent protection or the ability to market products, which could lead to a significant loss of sales, or otherwise materially affect future results of operations.

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive positions. While we protect our proprietary rights to the extent possible, we cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or techniques, or that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of our intellectual property would have an adverse effect on our competitive position and may cause us to incur substantial litigation costs.

If our business development activities are unsuccessful, our business could suffer and our financial performance could be adversely affected.

As part of our long-term growth strategy, we are engaged in business development activities including evaluating acquisitions, joint development opportunities, technology licensing arrangements and other opportunities. These activities may result in substantial investment of the company's resources. Our success developing products or expanding into new markets from such activities will depend on a number of factors, including our ability to find suitable opportunities for acquisition, investment or alliance; whether we are able to complete an acquisition, investment or alliance on terms that are satisfactory to us; the strength of the other company's underlying technology, products and ability to execute its business strategies; any intellectual property and litigation related to these products or technology; and our ability to successfully integrate the acquired company, business, product, technology or research into our existing operations, including the ability to adequately fund acquired in-process research and development projects. If we are unsuccessful in our business development activities, we may be unable to meet our financial targets and our financial performance could be adversely affected.

We are subject to risks associated with doing business globally.

Our operations, both inside and outside the United States, are subject to risks inherent in conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, loss of business in government and public tenders that are held annually in many cases, nationalization, increasingly complex labor environments, expropriation and other governmental actions, availability of raw materials, changes in taxation, importation limitations, export control restrictions, changes in or violations of U.S. or local laws, including the FCPA, dependence on a few government entities as customers, pricing restrictions, economic and political instability, disputes between countries, diminished or insufficient protection of intellectual property, and disruption or destruction of operations in a significant geographic region regardless of cause, including war, terrorism, riot, civil insurrection or social unrest. Failure to comply with, or material changes to, the laws and regulations that affect our global operations could have an adverse effect on our business, financial condition or results of operations.

We are subject to foreign currency exchange risk.

In 2011, we generated approximately 60% of our revenue outside the United States. We anticipate that revenue from outside the United States will continue to be significant. As a result, our financial results may be adversely affected by fluctuations in foreign currency exchange rates. Market volatility and currency fluctuations may limit our ability to cost-effectively hedge against our foreign currency exposure and, in addition, there are limitations in our ability to hedge our exposure to currency fluctuations in certain emerging markets. Governments may impose currency restrictions limiting our ability to manage our foreign currency exposure. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can mitigate these risks. A discussion of the financial impact of foreign exchange rate fluctuations, and the ways and extent to which we attempt to mitigate such impact, including the impact of restrictions on currency exchange imposed by the Venezuelan government, is contained under the caption "Financial Instrument Market Risk" in Item 7 of this Annual Report on Form 10-K.

Changes in tax laws or exposure to additional income tax liabilities may have a negative impact on our operating results.

Tax policy reform continues to be a topic of discussion in the United States. A significant change to the tax system in the United States, including changes to the taxation of international income, could have an adverse effect upon our results of operations. Because we operate in multiple income tax jurisdictions both inside and outside the United States, we are subject to tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision. However, there can be no assurance that we will accurately predict the outcome of these audits, and as a result the actual outcome of these audits may have an adverse impact on our financial results.

We may experience difficulties implementing our new global enterprise resource planning system.

We are engaged in a multi-year implementation of a new global enterprise resource planning system (ERP). The ERP is designed to accurately maintain the company's books and records and provide information to the company's management team important to the operation of the business. The company's ERP has required, and will continue to require, the investment of significant human and financial resources. We may not be able to successfully implement the ERP without experiencing significant delays, increased costs and other difficulties. Any significant disruption or deficiency in the design and implementation of the ERP could adversely affect our ability to process orders, ship product, send invoices and track payments, fulfill contractual obligations or otherwise operate our business. While we have invested significant resources in planning and project management, there is no assurance that a significant implementation issue will not arise.

We are increasingly dependent on information technology systems and infrastructure.

We increasingly rely upon technology systems and infrastructure. Our technology systems are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Likewise, data privacy breaches by employees and others with permitted access to our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. While we have invested heavily in the protection of data and information technology, there can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition of the company. In addition, there can be no assurances that a significant implementation issue may not arise as we continue to consolidate and outsource certain computer operations and application support activities.

If we fail to attract and retain key employees our business may suffer.

Our ability to compete effectively depends on our ability to attract and retain key employees, including people in senior management, sales, marketing and research positions. Competition for top talent in healthcare can be intense. Our ability to recruit and retain such talent will depend on a number of factors, including hiring practices of our competitors, compensation and benefits, work location, work environment and industry economic conditions. If we cannot effectively recruit and retain qualified employees, our business could suffer.

We are subject to a number of pending lawsuits.

We are a defendant in a number of pending lawsuits, including with respect to patent and product liability matters. In addition, we may be named as a defendant in future patent, product liability or other lawsuits. These current and future matters may result in reduced sales, significant liabilities and diversion of our management's time, attention and resources. Given the uncertain nature of litigation generally, we are not able in all cases to estimate the amount or range of loss that could result from an unfavorable outcome in these current matters. In view of these uncertainties, we cannot assure that the outcome of these matters will not result in charges in excess of any established reserves, and, to the extent available, liability insurance. We also continue to be self-insured with respect to product liability claims. The absence of third-party insurance coverage for current or future claims increases our potential exposure to unanticipated claims and adverse decisions. Protracted litigation, including any adverse outcomes, may have an adverse impact on the business, operations or financial condition of the company. Even claims without merit could subject us to adverse publicity and require us to incur significant legal fees. See Note 11 in Item 8 of this Annual Report on Form 10-K for more information regarding current lawsuits.

Current or worsening economic conditions may adversely affect our business and financial condition.

The company's ability to generate cash flows from operations could be affected if there is a material decline in the demand for the company's products, in the solvency of its customers or suppliers, or deterioration in the company's key financial ratios or credit ratings. Current or worsening economic conditions may adversely affect our business and the ability of our customers (including governments), to pay for our products and services, and the amount spent on healthcare generally. This could result in a decrease in the demand for our products and services, declining cash flows, longer sales cycles, slower adoption of new technologies and increased price competition. These conditions may also adversely affect certain of our suppliers, which could cause a disruption in our ability to produce our products. We continue to do business with foreign governments in certain countries, including Greece, Spain, Portugal and Italy, that have experienced a deterioration in credit and economic conditions. As of December 31, 2011, the company's net accounts receivable from the public sector in Greece, Spain, Portugal and Italy totaled \$524 million. The global economic conditions and governmental actions in these and other countries may continue to result in delays in the collection of receivables and require us to re-evaluate the collectibility and valuation of our receivables which could result in additional credit losses. These conditions may also impact the stability of the Euro. For more information on accounts receivable and credit matters with respect to certain of these countries, refer to the discussion under the caption entitled "Credit Facilities, Access to Capital and Credit Ratings" in Item 7 of this Annual Report on Form 10-K.

reviews are based on an estimated future cash flow approach that requires significant judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, foreign currency exchange rates, the selection of an appropriate discount rate, asset groupings, and other assumptions and estimates. The estimates and assumptions used are consistent with the company's business plans and a market participant's views of the company and similar companies. The use of alternative estimates and assumptions could increase or decrease the estimated fair values of the assets, and potentially result in different impacts to the company's results of operations. Actual results may differ from the company's estimates.

Stock-Based Compensation Plans

Stock-based compensation cost is estimated at the grant date based on the fair value of the award, and the cost is recognized as expense ratably over the substantive vesting period. Determining the appropriate fair value model to use requires judgment. Determining the assumptions that enter into the model is highly subjective and also requires judgment. The company's stock compensation costs primarily relate to awards of stock options, restricted stock units (RSUs), and performance share units (PSUs). The company uses the Black-Scholes model for estimating the fair value of stock options, and significant assumptions include long-term projections regarding stock price volatility, employee exercise, post-vesting termination and pre-vesting forfeiture behaviors, interest rates and dividend yields. The fair value of RSUs is equal to the quoted price of the company's common stock on the date of grant. The company uses a Monte Carlo model for estimating the fair value of PSUs, and significant inputs include the risk-free rate, volatility of returns and correlation of returns. Refer to Note 8 for additional information.

CERTAIN REGULATORY MATTERS

In July 2010, the FDA issued a final order regarding the recall of the company's COLLEAGUE infusion pumps currently in use in the United States. The company expects to complete the recall by July 2012. As discussed in Note 5, the company has recorded a number of charges in connection with its COLLEAGUE infusion pumps, including related to the FDA's order and other actions the company is undertaking outside the United States. It is possible that substantial additional cash and non-cash charges, including significant asset impairments related to the COLLEAGUE infusion pumps and related businesses, may be required in future periods based on new information, changes in estimates, the implementation of the recall in the United States, and other actions the company may be required to undertake in markets outside of the United States.

In June 2010, the company received a Warning Letter from the FDA in connection with an inspection of its Renal business's McGaw Park, Illinois headquarters facility. The Warning Letter pertains to the processes by which the company analyzes and addresses product complaints through corrective and preventative actions, and reports relevant information to the FDA. The company is working with the FDA to resolve these matters.

In January 2011, the European Medicines Agency (EMA) announced the review of Dianeal, Extraneal and Nutrineal PD solutions manufactured in the company's Castlebar, Ireland facility due to the potential presence of endotoxins in certain batches. In September 2011, the Committee for Medicinal Products for Human Use issued a positive opinion on the actions the company has taken to resolve the matter. In December 2011, the Article 31 referral procedure of the European Union Commission was formally closed allowing the Castlebar facility to begin supplying the European Union. The company is now in the process of transitioning the supply of Dianeal, Extraneal and Nutrineal for the European market from other manufacturing sites to the Castlebar facility.

While the company continues to work to resolve the issues described above, there can be no assurance that additional costs or civil and criminal penalties will not be incurred, that additional regulatory actions with respect to the company will not occur, that the company will not face civil claims for damages from purchasers or users, that substantial additional charges or significant asset impairments may not be required, that sales of other products may not be adversely affected, or that additional regulation will not be introduced that may adversely affect the company's operations and consolidated financial statements. Please see Item 1A of this Annual Report on Form 10-K for additional discussion of regulatory matters.

FORWARD-LOOKING INFORMATION

This annual report includes forward-looking statements, including statements with respect to accounting estimates and assumptions, litigation-related matters including outcomes, the recall of the company's COLLEAGUE infusion pumps, future regulatory filings and the company's R&D pipeline, strategic plans including with respect to the company's global, multi-year business transformation initiative, credit exposure to foreign governments, potential developments with respect to credit ratings, estimates of liabilities including those related to uncertain tax positions, contingent payments, future pension plan contributions, costs, discount rates and rates of return, the company's exposure to financial market volatility and foreign currency and interest rate risk, geographic expansion, business development activities, future capital and R&D expenditures, the impact of healthcare reform, the sufficiency of the company's financial flexibility, the adequacy of credit facilities, tax provisions and reserves, the effective tax rate in 2012, and all other statements that do not relate to historical facts. The statements are based on assumptions about many important factors, including:

- demand for and market acceptance risks for and competitive pressures related to new and existing products, such as ADVATE and plasma-based therapies (including Antibody Therapy), and other therapies;
- fluctuations in supply and demand and the pricing of plasma-based therapies;
- the impact of U.S. healthcare reform and other similar actions undertaken by foreign governments with respect to pricing, reimbursement, taxation and rebate policies;
- additional legislation, regulation and other governmental pressures in the United States or globally, which may affect pricing, reimbursement, taxation and rebate policies of government agencies and private payers or other elements of the company's business;
- future actions of third parties, including third-party payors, as healthcare reform and other similar measures are implemented in the United States and globally;
- the company's ability to identify business development and growth opportunities;
- product quality or patient safety issues, leading to product recalls, withdrawals, launch delays, sanctions, seizures, litigation, or declining sales;
- future actions of the FDA, EMA or any other regulatory body or government authority that could delay, limit or suspend product development, manufacturing or sale or result in seizures, injunctions, monetary sanctions or criminal or civil liabilities, including any sanctions available under the Consent Decree entered into with the FDA concerning the COLLEAGUE and SYNDEO infusion pumps;
- implementation of the FDA's final July 2010 order to recall all of the company's COLLEAGUE infusion pumps currently in use in the United States as well as any additional actions required globally;
- the company's ability to fulfill demand for SIGMA's Spectrum infusion pump;
- fluctuations in foreign exchange and interest rates;
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product development risks, including satisfactory clinical performance, the ability to manufacture at appropriate scale, and the general unpredictability associated with the product development cycle;

- the ability to enforce the company's patent rights or patents of third parties preventing or restricting the company's manufacture, sale or use of affected products or technology;
- the impact of geographic and product mix on the company's sales;
- the impact of competitive products and pricing, including generic competition, drug reimportation and disruptive technologies;
- inventory reductions or fluctuations in buying patterns by wholesalers or distributors;